IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

ROY WILMOTH, JR. **PLAINTIFF**

v. **CIVIL ACTION NO. 3:20-cv-120-NBB-RP**

ALEX M. AZAR, II, in his official capacity as Secretary of the U.S. Department of Health and Human Services **DEFENDANT**

DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiff has glioblastoma multiforme (GBM), a type of brain cancer. This case involves judicial review of the denial of Medicare claims for certain months of tumor treatment field therapy (TTFT) for the condition.[1] Plaintiff contends that the Secretary of the U.S. Department of Health and Human Services (Secretary) is forever collaterally estopped from denying Plaintiff's TTFT claims because an administrative law judge (ALJ) allowed coverage for certain months of TTFT. But Plaintiff is wrong on the law. The Medicare Appeals Council (Council) properly determined that there is no collateral estoppel here.

The doctrine of collateral estoppel does not apply to an administrative decision of this nature, and attempting to apply it would be inconsistent with the design of the Medicare program. Plaintiff is asking that a non-precedential decision from an ALJ forever estop the Secretary from denying Medicare claims for TTFT for Plaintiff. The Supreme Court in *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991), held that an administrative decision regarding an age discrimination claim did *not* have preclusive effect

[1] Plaintiff is not financially responsible for paying for the TTFT claims at issue if Medicare does not cover it. *See infra* § III.

because to apply collateral estoppel would be against Congress' intent in enacting the relevant statute. Giving preclusive effect to ALJ decisions would also interfere with the Secretary's discretion to permit case-by-case adjudication of Medicare claims. *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). A number of circuits follow the Supreme Court's reasoning and reject similar attempts to bind federal agencies to non-precedential decisions in administrative appeals.

To permit collateral estoppel would run contrary to the Medicare statute's presentment and channeling requirements. Moreover, even if there was no bar to collateral estoppel, Plaintiff fails to meet all four required elements. The issues in the ALJ decisions are not the same because the coverage determinations are each limited to specific time periods. The same issues were not actually litigated because the ALJ decision specifies that it applies only to the specific claims for Medicare coverage before him. In addition, because of limits on when the Secretary can appear in ALJ hearings, the Secretary did not have a full and fair opportunity to litigate the issues.

The Council also reviewed the evidence and determined that Plaintiff's claim must be denied because the Local Coverage Determination in effect provided that Medicare did not provide coverage for TTFT. The Council's decision is supported by substantial evidence and comports with the applicable law.

For all these reasons, summary judgment should be granted in the Secretary's favor.

II. STATUTORY AND REGULATORY BACKGROUND

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for the elderly and disabled. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment (DME) for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6); 42 C.F.R. Part 410. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage: "no payment may be made under . . . part B . . . for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. *Id.* The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program for the Secretary, has interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual (MPIM) § 13.5.4.[2]

To administer the "reasonable and necessary" standard, the Secretary employs a range of tools, from regulations to manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations (NCDs) "with respect to whether or not a

[2] The MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations

The Secretary delegates to CMS broad authority to determine whether Medicare covers particular medical services. 42 U.S.C. §§ 1395y(a), 1395ff(a), (f). CMS, in turn, contracts with Medicare Administrative Contractors (MACs). 42 U.S.C. § 1395kk-1. A MAC makes coverage determinations, issues payments, and develops local coverage determinations (LCDs) for the geographic area it serves, 42 U.S.C. § 1395ff(f)(2)(B), under the reasonable and necessary provisions of § 1395y(a)(1). 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the MAC that issued it. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, a MAC follows program guidance. The MPIM requires that an LCD specify when "an item or service is considered to be reasonable and necessary." MPIM § 13.5.4. A MAC develops an LCD by considering the medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1, 13.5.3, 13.5.5; 66 Fed. Reg. 58,788 (Nov. 23, 2001). The MAC also follows detailed procedures for issuing new or revised LCDs, including engaging in a comment-and-notice period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

C. The LCD for TTFT Devices

In April 2011, the Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune), manufactured by Novocure, for the treatment of GBM. AR at 333. Following an open meeting and solicitation of public

comments, in August 2014, the Medicare program's DME MACs issued the original LCD for TTFT. This LCD stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." AR at 004. This LCD remained in effect during the dates of service for the Medicare claims at issue in this case. *Id.*

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR at 218-220. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. AR at 052-073.

D. Medicare Claim Appeals

In order to challenge a denial of a Medicare claim, a beneficiary must pursue several levels of administrative appeal before he may come before a district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the beneficiary seeks a redetermination from the MAC. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. Next the beneficiary seeks reconsideration by a qualified independent contractor (QIC) 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). The next level of review is a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the record. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ's decision by the Medicare Appeals Council.. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation of his appeal to district court. 42 C.F.R. § 405.1132. The Council's decision (or the ALJ decision, if there is no review by the Council) represents the final decision of the

Secretary for purposes of administrative exhaustion and judicial review. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136.

The beneficiary is entitled to review of the Secretary's decision in the district court "as is provided in [42 U.S.C. §] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). Under review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

E. Advanced Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with written notice (Advance Beneficiary Notice) of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b).

III. FACTUAL AND PROCEDURAL BACKGROUND

This case arises from the denial of Plaintiff's claims for Medicare coverage of certain months of TTFT using the Optune system. Plaintiff was diagnosed with glioblastoma in February 2016 and was prescribed TTFT, a treatment delivered through the rental of the Optune system from Novocure, Inc. Docket 33, pp. 4-5.

On May 7, 2019, ALJ Kenneth Bryant entered an order denying Plaintiff's claims for TTFT with dates of service from April 19, 2018 through June 19, 2018. AR at 019-025. ALJ Bryant found that Medicare did not cover the device, and held the supplier financially responsible for the non-covered cost. AR at 025.

Plaintiff appealed ALJ Bryant's decision to the Council. AR at 075-079. Plaintiff noted two prior favorable ALJ decisions and argued that the Secretary was collaterally estopped from relitigating the coverage issue. *Id*. at 79.

On October 15, 2019, the Council issued a decision that upheld ALJ Bryant's decision. AR at 003-008. The Council held that collateral estoppel did not apply to bar the Council from denying Plaintiff's claims. AR at 007. The Council also held the *supplier* [Novocure] financially responsible for the non-covered costs. *Id*. at 008. The MAC did not hold Plaintiff himself financially responsible for any non-covered costs. *Id*.

Plaintiff filed this case under 42 U.S.C § 405(g), seeking judicial review of the MAC's October 15, 2019 decision. Docket 33. After being severed and transferred from the District Court of the District of Columbia, Plaintiff filed an Amended Complaint here on May 21, 2020. Docket 33. On August 10, 2020, the Secretary filed a Motion to Dismiss Plaintiff's Amended Complaint based on Plaintiff's lack of standing. Docket 42. That motion is ripe and pending before this Court.

Plaintiff contends that the Council's decision should be overturned because several ALJs found that Medicare coverage for the Optune System on various dates of service was appropriate for Plaintiff. Docket 33 at ¶¶ 1, 20-26

IV. STANDARD OF REVIEW

Judicial review of the Secretary's final decision is limited to whether the decision comports with applicable law and is supported by substantial evidence. 42 U.S.C. § 1395ff(b), incorporating 42 U.S.C. § 405(g)). Substantial evidence is "more than a scintilla, but less than a preponderance." *Richardson v. Perales*, 402 U.S. 389, 401 (1971). In conducting its review, the court "may only scrutinize the record." *Leggett v. Chater*, 67 F.3d 558, 564 (5th Cir. 1995) (citations omitted). The court may not re-weigh the evidence, try the issues *de novo*, or substitute its judgment for that of the Secretary. *Carey v. Apfel*, 230

F.3d 131, 135 (5th Cir. 2000) (citation omitted). In the face of substantial evidence, the court must affirm the Secretary's decision even if the court "might have reached a different conclusion." *Dubose v. Mathews*, 545 F.2d 975, 977 (5th Cir. 1977). In short, a court's review of a final agency decision under 42 U.S.C. § 1395ff(b), incorporating 42 U.S.C. § 405(g), is "highly deferential." *Miss. Care Ctr. of Morton, LLC v. Sebelius*, 449 Fed. App'x 341, 344, (5th Cir. Oct. 25, 2011).

V. ARGUMENT

A. Collateral Estoppel is Inapplicable in Medicare Claim Appeals.

The Council correctly held that it was not barred from denying Plaintiff's Medicare claims based on collateral estoppel. AR at 007. The Supreme Court's decision in *Astoria* explains that preclusion cannot apply when there is a statutory purpose to the contrary: "Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand[,] ... [and] the question is not whether administrative estoppel is wise but whether it is intended by the legislature." *Astoria*, 501 U.S. at 108; *Stafford v. True Temper Sports*, 123 F.3d 291, 294 (5th Cir. 1997) (holding that if "Congress manifests an intent, pursuant to a statutory scheme, that state administrative decisions have no such preclusive effect, collateral estoppel is not to be applied" to give agency's fact finding preclusive effect). Here, the Medicare statute and regulations indicate a clear intent to bar the application of collateral estoppel to ALJ decisions.

1. The applicable Medicare regulations provide that ALJ decisions do not bind the Secretary in future cases.

The Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions. The Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and all other decisions, which are non-precedential and are not binding. Only Council decisions have the

potential to become precedential, and this occurs only when they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. These must be made available to the public, with personally identifiable information removed, with notice published in the Federal Register. 42 C.F.R. § 401.109(b). The decision is then given "precedential effect" and is binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c). The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
>
> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect.

Here, no Council decision, much less one designated as precedential, has favorably decided any of Plaintiff's Medicare claims for TTFT. Accordingly, nothing in the Medicare statute or regulations binds the Secretary to approve Plaintiff's TTFT claims. *Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions finding that the device at issue was "reasonable and necessary" or "safe and effective").

The regulations on LCDs offer further support that ALJ decisions are nonbinding and therefore collateral estoppel does not apply. Plaintiff's collateral estoppel argument relies upon favorable ALJ decisions that departed from the LCD and approved TTFT

treatment.[3] But an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b) (all emphasis added). The regulations reaffirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). "Nowhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device." *Almy*, 679 F.3d at 310. ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC level of review. 42 C.F.R. § 405.968(b)(1) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions would also run contrary to the Medicare statute, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B) (emphasis added); *Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019) ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved."). If a favorable ALJ ruling were to collaterally estop the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a *de novo* review; instead, the Council would be bound to accept the ALJ's conclusions. *Almy*, 679 F.3d at 303 (Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

The Medicare regulations direct that ALJ decisions are not to be accorded conclusive effect as they are non-precedential, and the Council's *de novo* review provided by the

[3] ALJs are not bound by LCDs, but are required to afford them "substantial deference." 42 C.F.R. § 405.1062(a).

Medicare statute means the Council is free to make an independent determination. Accordingly, the Medicare statute and regulations bar the application of collateral estoppel to the decisions of ALJs.[4] *Astoria*, 501 U.S. at 111–12 (rejecting application of collateral estoppel to a federal statute because applying the principle would render a section of that statute superfluous).

2. Applying collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute.

If ALJ decisions were deemed binding, they would also interfere with the deference and discretion afforded to the Secretary to implement the Medicare statute's "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries. "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to [his] judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court foreclosed interference with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the

[4] To the extent that Plaintiff argues that ALJ decisions rendered after the Council's decision form the basis for collateral estoppel, those decisions were not before the Council and could not have possibly been considered by the Council. 42 U.S.C. § 405(g) provides that the court may enter a judgment "upon the pleadings and transcript of the record." The court's review is limited to the record that was before the Council. *Lovett v. Schweiker*, 667 F.2d 1, 3 (5th Cir. 1981) (holding that "No evidence external to the administrative record is generally admissible in reviewing an administrative action pursuant to 42 U.S.C. 405(g)."); *Cross Terrace Rehab, Inc., LLC v. Sec'y, Dep't of Health & Human Servs.*, 797 Fed. Appx. 503, 507 (11th Cir. 2020) (The court's function "in conducting this review is to determine whether there was a reasonable basis for the decision in light of the relevant legal standards and the facts known to the agency *at the time the decision was made*.") (emphasis added).

means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617.

The Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Medicare Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, will have a right of review on any later claims. The application of collateral estoppel, therefore, is fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiff's view, once a claim is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Docket 33. Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. It is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

A number of appellate courts, including the Fifth Circuit, reject attempts to bind federal agencies to non-precedential decisions rendered in lower-level administrative appeals. In *Homan & Crimen, Inc. v. Harris*, the Fifth Circuit considered the preclusive effect of decisions of the Provider Reimbursement Review Board on other decisions made by the Secretary. 626 F.2d 1201, 1205 (5th Cir. 1980). As the Fifth Circuit noted, the Secretary may review a decision of the PRRB. *Id.* The Court held that "the decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling." *Id.*

In *Almy*, a plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303. The Fourth Circuit noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. The court should reject Plaintiff's attempt to elevate non-precedential ALJ opinions into binding coverage rules, which would "stultify the administrative process." *See id.* (quoting *Chenery*, 322 U.S. at 202).

The Fourth Circuit noted that other circuits concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). The D.C. Circuit emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g.*, *Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) ("unappealed" ALJ rulings could not estop the United States because such rulings were not

binding on the agency or even on other ALJs, and noting that the lack of appeal did not "elevate them to the level of a binding final agency action.").

The Ninth Circuit adopted the reasoning of *Almy*, reversing a district court decision that had "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012). Likewise, the Seventh Circuit recognized that lower-level decisions may conflict and they do not bind the Secretary. *Abraham Mem'l Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, *any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court*." *Almy*, 679 F.3d at 311 (emphasis added). The doctrine of collateral estoppel cannot transform an ALJ ruling from what it is, a single decision by an intermediate-level tribunal that is binding only in a single case, to what it is not, an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. Collateral estoppel is contrary to the Medicare Act's presentment and channeling requirements.

To the extent Plaintiff seeks to have the Secretary collaterally estopped as to future claims for TTFT, the D.C. Circuit recently held in *Porzecanski* that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief mandating

that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." 943 F.3d at 475.

The facts in *Porzecanski* are similar to those here. Porzecanski suffered from a life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. After beginning treatment, the plaintiff remained symptom-free, and his physicians recommended that he continue the monthly treatment indefinitely. *Id.* at 476-77. After one of his Medicare claims was denied at the ALJ level and the Council did not render a decision within the required time frame, he sought review by a district court. *Id.* at 477. Plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be met: "[T]he Secretary has not decided [plaintiff's] future claims because – to state the obvious – none has been submitted." *Id.*

The court also rejected plaintiff's request to *preclude* the Secretary from concluding that the claims on appeal were not covered by Medicare and were not medically necessary – the identical relief that Plaintiff seeks here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Medicare decisions by the Supreme Court: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was

'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S. at 620-21). Likewise, in *Illinois Council*, the Court again declared that a "claim for future benefits is a § 405(h) claim" and that "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing 529 U.S. at 12).

The D.C. Circuit concluded that "*Ringer* and *Illinois Council* directly foreclose [Porzecanski's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id.* at 483. Here, Plaintiff's assertion that the Secretary is estopped from denying his future claims for TTFT "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *See id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiff cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *See id.* at 483-84.

E. The Elements of Collateral Estoppel are Not Met.

Even if collateral estoppel could be invoked in this case, the elements have not been met. As the party invoking collateral estoppel, it is Plaintiff's burden to show that:

> (1) the issue at stake is identical to the one involved in the prior proceeding;
> (2) the issue was actually litigated in the prior proceeding;
> (3) the determination of the issue in the prior litigation must have been "a critical and necessary part" of the judgment in the first action; and
> (4) the party against whom collateral estoppel is asserted must have had a full and fair opportunity to litigate the issue in the prior proceeding.

Wehling v. CBS, 721 F.2d 506, 508 (5th Cir. 1983). Plaintiff cannot carry his burden on the first, second, and fourth elements of collateral estoppel.

1. The issues are not identical.

First, the issues decided in Plaintiff's claim appeals were different, because each concerned whether TTFT was covered under Medicare for a *specific period in time*. Docket 33, ¶ ¶ 20-26. Both the Council decision's to deny Plaintiff's claim and the ALJ decisions that approved other claims limited their respective decisions to the coverage dates under

appeal.[5] AR at 008 (October 15, 2019 Council's Decision) (denying coverage for dates of service of April 19, 2018 through June 19, 2018); AR at 050 (July 2, 2019 ALJ Decision) (approving coverage for dates of service July 19, 2018 through September 19, 2018); AR at 156,166 (December 13, 2018 ALJ Decision)(approving coverage for dates of service September 19, 2017 through December 19, 2017). Because the favorable ALJ decisions did not adjudicate whether Medicare coverage existed for any other claims, the first element of collateral estoppel is not present. *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*,435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods).

2. The same issue was not actually litigated.

As to the second element, the differing time periods covered by each ALJ decision means that the same issue was not actually litigated. The favorable ALJ decision explicitly limited the time period of the coverage decision, as do the Medicare regulations limiting the precedential effect of ALJs declining to follow an LCD, 42 C.F.R. § 405.1062(b). AR at 050, 156, 166. As such, Plaintiff cannot meet the second element. *Donovan v. Fed. Clearing Die Casting Co.*, 695 F.2d 1020, 1022 (7th Cir. 1982) (issue not actually litigated when issue left expressly undecided by decision); *Interoceanica v. Sound Pilots*, 107 F.3d 86, 91–92 (2nd Cir. 1997) (issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *California Communities Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (fissues not actually litigated where court stated it did "need not address" the issue).

[5] Although Plaintiff cites to additional ALJ decisions in the Amended Complaint, there are only two ALJ decisions contained in the administrative record. AR at 50, 156.

3. The Secretary was not fully represented in the prior action.

Finally, the fourth element is not met because the Secretary's opportunity to litigate is limited in Medicare coverage appeals. The Secretary has no opportunity to participate during the first (redetermination) and second (QIC) levels of the appeal process. 42 C.F.R. §§ 405.948, 405.968; *also see Genesis Health*, 798 F. Supp. 2d at 182 ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions."). And the Secretary's participation is limited in ALJ appeals. When a beneficiary is unrepresented, the Secretary cannot be a party to the hearing, and thus has no opportunity to litigate. 42 C.F.R. § 405.1012(a). Furthermore, if the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings simply move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate thousands of appeals annually filed by providers and represented beneficiaries. 42 C.F.R. §§ 405.1010(a), 405.1012; 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting 650,000 pending ALJ appeals as of September 2016).

If the Secretary does not become a party to an ALJ hearing, the Secretary cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate at every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Therefore, as the Secretary's opportunity to appeal was also extremely limited, there was not a full and fair opportunity to litigate.

4. A lack of incentive to litigate ALJ decisions weighs against preclusion.

Courts have also recognized an exception to applying preclusion even where all the elements for estoppel are met. Where there is an incentive against extensively litigating smaller matters (because cost outweighs the size of the issue), it is unfair to allow the decisions in those smaller matters to have large preclusive effects. Such is the case here, where the Secretary's involvement in the litigation of every Medicare claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and nonprecedential ALJ decisions should not be given preclusive effect, which would result in great cost to the Medicare Trust. *Rawls v. Daughters of Charity of St. Vincent De Paul*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital "had far less incentive to contest the unlawfulness of the plaintiff's detention than at present"); *Power Integrations v. Semiconductor Components Indus.*, 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019)(the exception of "a lack of opportunity or incentive to litigate the first action" prevented preclusion where there was a disparity in incentives to appeal an issue).

5. Even if collateral estoppel applied, it would have no force after the new LCD became effective on September 1, 2019.

Even if collateral estoppel applied here, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when there has been a change in essential facts. *Montana v. United States*, 440 U.S. 147, 159 (1979) ("It is, of course, true that changes in facts essential to a judgment will render collateral estoppel inapplicable in a subsequent action raising the same issues."); *E.E.O.C. v. Am. Airlines, Inc.*, 48 F.3d 164, 168 (5th Cir. 1995) (to avoid the preclusive effect of a prior determination, "a change must have occurred in facts that were essential to the

judgment and were of controlling significance.") (quotation marks removed). Here, there was a significant change between the old LCD, which categorically denied coverage for TTFT, and the new LCD, which allowed coverage of TTFT under certain circumstances. AR at 052-073. Accordingly, if Plaintiff were to prevail on collateral estoppel, the only decision that might be estopped would be the October 15, 2019 Council decision denying Plaintiff's claims for TTFT. Further preclusive or injunctive relief would not be warranted, because the new LCD has already been in place for a number of months now.

Along the same lines, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, *indefinitely* into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or even dangerous if continued (*e.g.*, when a patient suffers serious side effects). Even if Plaintiff's medical history remained unchanged for several years, it would still be speculation to assume the facts would remain unchanged for any Medicare claim he might file in the future. For example, if Plaintiff filed claims for coverage, but the evidence showed that he was not actually using the device, Medicare should not be required to approve the claims. AR at 1200 (current LCD requires that beneficiary "use TTFT for an average of 18 hours per day").

Because the controlling facts and law have changed, applying collateral estoppel would not benefit Plaintiff, who is not financially responsible for the claims on appeal. Meanwhile, a finding that favorable ALJ decisions have preclusive effect would have widespread, negative ramifications for the Medicare program, and the many millions of Americans it serves. Collateral estoppel is fundamentally inconsistent with the terms of the Medicare Program, and the court should grant summary judgment for the Secretary.

F. To the Extent Plaintiff Makes Any Other Arguments for Reversal in His Motion, Those Arguments Fail

It appears that Plaintiff intends in his motion for summary judgment to raise the sole argument that the Council was barred by collateral estoppel from denying coverage for the period at issue. Docket 33.[6] If Plaintiff's motion is limited to that argument, any other arguments are waived. *United States v. Whitfield*, 590 F.3d 325 (5th Cir. 2009) (party generally waives any argument that it fails to brief on appeal).

Even if Plaintiff's motion does raise the other arguments referenced in the complaint, those arguments fail. Plaintiff's sole claim under 42 U.S.C. § 405(g) is that the Council's decision was contrary to law, arbitrary and capricious, an abuse of discretion and unsupported by the record. Docket 33 at ¶ 31-32. The remainder of the claims in Plaintiff's complaint are asserted under the Administrative Procedure Act (APA). Docket 33 at ¶¶ 33-42. The APA does not apply herebecause this appeal is taken under 42 U.S.C. § 1395ff(b), which permits judicial review in accordance with 42 U.S.C. § 405(g). Section 405(g), in turn, provides for review under the substantial evidence standard—not any other standard that may be provided for by the APA. *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (Section 405(g) cases are not governed by the APA standard of review); 5 U.S.C. § 704 (providing for review of agency actions only where there is "no other adequate remedy in a court"). But even if the APA did apply, there is no evidence to suggest that the ALJ's decision was "unlawfully withheld or unreasonably delayed"; "arbitrary and capricious, [an] abuse of discretion, [or] not in accordance with law"; "in excess of statutory jurisdiction,

[6] Specifically in Plaintiff's prayer for relief he asks the court to enter an order "(1) finding that the Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiff is a covered benefit; (2) finding that, in light of the prior decisions granting coverage, the denial at issue in this case is arbitrary and capricious; and, (3) directing the Secretary to cover the claim at issue in this case…" Docket 33 at p. 11.

authority, or limitations or short of statutory right"; or "without observance of procedure required by law." Docket 33 at ¶¶ 33-40.

The Council reviewed the evidence in the record and held that it was appropriate to defer to the LCD in effect on the dates of service at issue under the circumstances in this case. AR at 004. The Council considered Plaintiff's argument that the LCD's evidentiary sources are inadequate and incomplete. The Council noted that "Congress had created a separate appeals process for challenging the validity of LCDs pursuant to § 1869(f)(2)(A) of the Act." AR at 005. 42 C.F.R. §§ 426.418, 426.419. AR at 005. Thus, the Council did not have the authority to invalidate the LCD itself. AR at 0006. The Council also considered Plaintiff's argument that TTFT should be covered because "the beneficiary's treating physician prescribed the device and significant reliance should be placed on that determination." AR at 006. The Council rejected Plaintiff's argument and cited to CMS Ruling 93-1 that provides that "a physician's opinion will be evaluated in the context of the evidence in the complete administrative record." AR at 006. The Council declined to set aside the LCD based on Plaintiff's prescription for the device. AR at 006. There is "such relevant evidence as a reasonable mind might accept as adequate to support" the conclusion that coverage was not warranted in this case. *Richardson*, 402 U.S. at 401.

VI. CONCLUSION

The Secretary requests that the court grant his motion for summary judgment.

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